

REMARKS

As a result of a telephone conversation between Examiner David Lukton and the Applicant's below-named representative on December 7, 2009, it is understood that claims 4 and 6 have not been examined. Claims 4 and 6 are not rejected in the outstanding Office Action. It is additionally recognized that no explanation of a grounds for objection to claims 4 and 6 has been provided in the outstanding Office Action. It is requested that Examiner Lukton examine claims 4 and 6.

The outstanding Office Action includes several prior art-based rejections. Each of these prior art-based rejections is discussed in turn.

The invention according to independent claim 1 is directed at a biodegradable barrier network. The biodegradable barrier network comprises a cationic polypeptide, an anionic polypeptide, and a pharmaceutically acceptable carrier.

The references relied upon in the outstanding Office Action are not directed at providing a biodegradable barrier network. The biodegradable barrier network according to the present invention provides a biological effect such as tissue binding of cationic polypeptides, in the form of polylysine or polyarginine, so that the tissue exposes positively charged groups which form a biosurface-attached mechanical barrier *in vivo* by the addition of an anionic polypeptide. Additional secondary effects are that this barrier network inhibits adhesion and that this barrier network is biodegradable. None of the references relied upon in the outstanding Office Action acknowledges or even hints at the sequential adding of the cationic and anionic peptides, and none of the references disclose a biodegradable barrier network according to the presently claimed invention.

Claim 1 stands rejected under 35 U.S.C. § 103 based on obviousness over U.S. Patent No. 5,246,707 to Haynes. This rejection is traversed.

Haynes discloses sustained release phospholipid-coated formulations. See Haynes at column 3, lines 20-45. The outstanding Office Action refers to Haynes at column 4, line 60+, for the disclosure of "an equal weight mixture of polyarginine and polyglutamic acid." See page 3 of the outstanding Office Action. This portion of Haynes is directed at precipitation of the bio-molecule. According to Haynes:

"In the case where none of the above strategies works to precipitate the

bio-molecule it will be possible to remove it from solution by precipitation with an equal weight mixture of cationic and anionic polypeptides, such as polyarginine and polyglutamic acid.”

See Haynes at column 4, lines 57-62. Clearly, there is no disclosure of a biodegradable barrier network, and there is no disclosure of a pharmaceutically acceptable carrier. The outstanding Office Action fails to explain why one skilled in the art would modify Haynes to provide a mixture of cationic and anionic polypeptides in a pharmaceutically acceptable carrier to provide a biodegradable barrier network according to the presently claimed invention.

In view of the above comments, the claimed invention is not anticipated and would not have been obvious from Haynes. Accordingly, withdrawal of the rejection is requested.

Claim 1 stands rejected under 35 U.S.C. § 103 over U.S. Patent No. 4,378,224 to Nimni et al. This rejection is traversed.

Nimni et al. disclose a coating for heart valves and other prosthetic devices intended to be implanted. See Nimni et al. at column 1, lines 65-68. The composition is a mixture that exists only temporarily during the manufacturing process, and will be covalently linked to the implant tissue. The outstanding Office Action refers to claims 24 and 44 of Nimni et al. Claim 24 lists several polyelectrolytes and claim 44 provides that the “gap filing material is a polyelectrolyte.” The reference by the outstanding Office Actions to claims 24 and 44 of Nimni et al. is not understood. The mixtures described by Nimni et al. do not include a pharmaceutically acceptable carrier, and are not biodegradable barrier networks according to the presently claimed invention. Furthermore, the outstanding Office Action fails to explain why one having ordinary skill in the art would modify Nimni et al. to achieve the presently claimed invention.

In view of the above comments, the claimed invention is not anticipated and would not have been obvious from Nimni et al., and withdrawal of this rejection is requested.

Claim 1 stands rejected under 35 U.S.C. § 103 over U.S. Patent No. 7,101,947 to Schlenoff et al. This rejection is traversed.

Schlenoff et al. disclose a polyelectrolyte film formed from a polylysine and polyglutamate complex as multilayers, which is used for chiral separation in vitro. See Schlenoff et al. at column 2, line 37 through column 4, line 44. The outstanding Office Action refers to Schlenoff et al. at column 15, line 8+, and claim 10, for the disclosure of

a "mixture that comprises poly-Lys and poly-Glu." See page 3 of the outstanding Office Action. Schlenoff et al., however, fail to disclose the presence of a pharmaceutically acceptable carrier, and the outstanding Office Action fails to explain why one having ordinary skill in the art would have received a suggestion to modify Schlenoff et al. to include a pharmaceutically acceptable carrier in order to provide a biodegradable barrier network according to the presently claimed invention.

In view of the above comments, the claimed invention is not anticipated and would not have been obvious from Schlenoff et al., and withdrawal of the rejection is requested.

Claims 1-3, 5, 7 and 8 stand rejected under 35 U.S.C. § 103 over "Isoelectric Focusing, Principles and Methods," *Pharmacia Fine Chemicals*, Uppsala Sweden, 1982, pp. 128-129. This rejection is traversed.

"Isoelectric Focusing, Principles and Methods" fails to disclose a biodegradable barrier network in accordance with the present claim 1. The outstanding Office Action refers to "Isoelectric Focusing, Principles and Methods" for the disclosure that:

"marker proteins can be used to assist in the determination of the isoelectric point of a given protein. As described, the marker proteins can span a range of isoelectric points, e.g., from pI 4.5 to pI 8.5."

See pages 3 and 4 of the outstanding Office Action. It is pointed out, however, that there is no disclosure of a pharmaceutically acceptable carrier so that a biodegradable barrier network can be obtained according to the presently claimed invention. Furthermore, the outstanding Office Action fails to explain why one having ordinary skill in the art would have received a suggestion to modify "Isoelectric Focusing, Principles and Methods" to achieve the presently claimed invention.

In view of the above comments, the claimed invention is not anticipated and would not have been obvious from "Isoelectric Focusing, Principles and Methods."

It is believed that this application is in condition for allowance. Early notice to this effect is earnestly solicited.



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Respectfully submitted,

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By

A handwritten signature in dark ink, appearing to read "Dennis R. Daley". The signature is written over a horizontal line.

Dennis R. Daley
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DRD/mls